EXHIBIT D

In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 19-2875

Expert Report of Edward H. Kaplan, M.D. in
Support of Plaintiffs' Motion for Class Certification

Dear Mr. Slater:

I have evaluated the question of whether and to what extent medical monitoring would be appropriate for the people who used valsartan containing drugs ("VCD's" or "valsartan") contaminated with an International Agency for Research on Cancer ("IARC")- and Environmental Protection Agency ("EPA")-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA"). At your requests, I have reviewed scientific literature, regulatory documents and other documents, and applied my knowledge, education and experience in order to outline and summarize the issues and approach to organizing a screening and monitoring program for class members exposed to VCDs that were contaminated with NDMA and/or NDEA. In addressing these questions, I've relied upon the materials detailed below. All opinions are stated to a reasonable degree of medical certainty.

1. Expert Background and Qualifications

I, Edward H. Kaplan, M.D. am a board-certified medical oncologist. I am familiar with the standard of care for cancer treatment by way of my training and experience. In my practice, I have designed screening programs for the patients I treat and frequently monitor patients at high risk for cancer or cancer recurrence. I received my Doctor of Medicine degree at Loyola-Stritch School of Medicine in Maywood, Illinois and I subsequently completed my internship and residency training for internal medicine at Northwestern University Medical School in Chicago, Illinois. I continued training there in hematology and oncology, receiving the Galter Fellowship and Bill Veek Fellowship. After completing my fellowship, I joined the faculty at Rush University in Chicago, Illinois. I was later the cofounder and director of the Comprehensive Center for Gastrointestinal Malignancies at the Rush Cancer Institute. I was subsequently appointed as Chairman of the Department of Hematology and Oncology at Rush North Shore Medical Center in Skokie, Illinois. In addition, I serve as Assistant Professor of Medicine at Rush Medical College in Chicago, Illinois. I have presented at leading scientific meetings across the nation and am an author on over 60 research articles.

A more detailed description of my qualifications, including a list of all publications authored in the previous 10 years, is provided in my Curriculum Vitae, in Attachment A. Attachment B lists the materials I considered for this report. I am compensated for this matter at an hourly rate. This compensation is not contingent upon the outcome of this matter. The opinions I state in this report are stated within a reasonable degree of professional certainty. My analysis of the issues at hand is ongoing. I reserve the right to respond to, rebut, opine on, or incorporate opinions offered by other experts in these matters. I reserve the right to modify or supplement this report based on new materials or testimony that may become available to me, including, but not limited to, other expert witness reports.

2. Class-Wide Applicability

In forming my opinions, I have assumed that the people who took the valsartan in question can be identified, along with identification of the manufacturers of their pills, the dosage and levels of NDMA/NDEA, and duration of use. I have also assumed that the medical monitoring fund/program to be established can be efficiently administered to ensure that people will only receive funding for appropriate tests or interventions.

3. Background

It has been established that valsartan API (active pharmaceutical ingredient) manufactured by ZHP, Hetero, Mylan, and Aurobindo, and also sold to Teva and Torrent for use in the manufacture of finished valsartan drugs sold by those companies, was contaminated with carcinogens, NDMA and NDEA. It is my understanding that this contamination occurred in two general ways: as a by-product of the API manufacturing processes, and/or due to use of contaminated solvents or inadequate cleaning of manufacturing equipment.

The initial step in constructing this monitoring protocol was identification of the cancers at issue. Based on my review of the reports of Dr. Panigrahy, Dr. Madigan, Dr. Etminan, and Dr. Lagana, the following cancers merit monitoring:

1. Liver
2. Stomach
3. Colorectal/Intestinal
4. Esophageal
5. Lung
6. Prostate
7. Bladder
8. Pancreatic
9. Blood (Leukemia, NHL and Multiple Myeloma)

4. Assumptions on Contaminant Levels and Thresholds for Monitoring

In conducting this analysis, I assumed that the Plaintiffs' experts are correct that the levels, dosages, and duration of use were/are sufficient to increase one's risk of certain cancers, and to cause or contribute to causing cancer in users, and I have prepared this report consistent with those assumptions.

In order to qualify for medical monitoring, class members must have ingested a cumulative amount of NDMA from both the valsartan pills and their diet that they have reached the Lifetime Cumulative Exposures associated with statistically significant increased risks in dietary and other studies. The Lifetime Cumulative Exposures in dietary and other studies have been determined by Madigan and Panigrahy. The classes have been defined in the operative medical monitoring complaint as:

> All individuals residing in Alaska, Arizona, Colorado, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Maine, Massachusetts,

> Minnesota, Missouri, Montana, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, West Virginia, Wyoming and who consumed a sufficiently high Lifetime Cumulative Threshold of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since January 1, 2012. This is the "Medical Monitoring Independent Claim Class."
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> and
>
> All individuals residing in every state, territory, and possessions of the United States of America except Mississippi and who consumed a sufficiently high Lifetime Cumulative Threshold of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since January 1, 2012. This is the "Medical Monitoring Remedy Class."

For both the Medical Monitoring Independent Claim Class and Medical Monitoring Remedy Class, the determination of whether the class member consumed a Lifetime Cumulative Threshold ("LCT") sufficient for class membership is based on objective and ascertainable factors.

Specifically, (A) at a dose of 320 mg, the class member needs to have taken a combination of three (3) months of ZHP API, OR 18 months of Hetero API, OR 54 months of Mylan and/or Aurobindo API; (B) at a dose of 160 mg, the class member needs to have taken a combination of six (6) months of ZHP API, OR 32 months of Hetero API, OR 108 months of Mylan and/or Aurobindo API; (C) at a dose of 80 mg, the class member needs to have taken a combination of 12 months of ZHP API, OR 64 months of Hetero API, OR 216 months of Mylan and/or Aurobindo API; and (D) at a dose of 40 mg, the class member needs to have taken a combination of 24 months of ZHP API, OR 128 months of Hetero API, OR 432 months of Mylan and/or Aurobindo API;

The reference to combination above means that the class member need not have only taken Valsartan manufactured solely by one manufacturer. For example, by way of illustration only, a class member who was prescribed 320 mg and who consumed two (2) months of ZHP API and six (6) months of Hetero API qualifies.

5. Opinion on Medical Monitoring

Identifying a malignant cancer early in its' development is vital to ensure that the subject receives treatment in a timely fashion, therefore affording a better chance of control and cure. I considered specificity/possibility of type 1 and 2 errors/invasiveness/risks and benefits of monitoring. It is my opinion to a reasonable degree of medical certainty that there exist diagnostic tests that can mitigate the risks of developing cancer faced by the class of people because of their exposure to contaminated valsartan (who have a level of exposure greater than or equal to the LCT), and that this program is different than the one that would have been

prescribed in the absence of that particular exposure and increased risk. Furthermore, it is my opinion that this monitoring is both reasonable and necessary.

This program includes routine screening for asymptomatic individuals as follows:

1. **Annual History/Physical and laboratory studies** by *Internist, Family Practitioner or Medical Oncologist*:

   A. History to include questions directed towards signs / symptoms of malignancy (i.e.: Shortness of breath, cough, blood in stools, pain, weight loss, cough, other issues)

   B. Physical Exam to be routine but to focus on lymph nodes, abdomen, breast, lungs, thyroid.

   C. Lab tests to include blood smear evaluation (CBC), Basic chemistry Profile ("CMP")- which includes liver enzymes, Kidney function, labs for general signs of inflammation or imbalances, thyroid function tests, PSA (for males) and urinalysis.

2. **Specialized Testing:**

   Annual or more often based on clinical parameters per monitoring:

   A. Galleri® (Grail's multi-cancer early detection blood test) or similar liquid biopsy testing performed annually. This is a targeted methylation-based cell-free DNA test that has been clinically validated:
   The Circulating Cell-free Genome Atlas study was a prospective, case-controlled, observational study and demonstrated that a blood-based test utilizing cell-free DNA (cfDNA) sequencing in combination with machine learning could detect cancer across multiple cancer types and predict cancer with high accuracy. It has validated this testing for use as a screening tool. Specificity for cancer signal detection was 99.5% [95% confidence interval (CI): 99.0% to 99.8%]. Galleri has FDA Breakthrough Device Designation.

   B. Cologuard or similar fecal testing for colon cancer annually and can start at any age.

   C. Periodic testing - based on established monitoring guidelines
   -Colonoscopy (every 5 years as for screening in moderately high risk patients)
   -Upper Endoscopy (every 5 years or based on symptoms, smoking and alcohol history)
   -Low Dose CT Chest Scan annually (especially in smokers or prior smokers)

Further screening for symptomatic patients or those with abnormalities uncovered by the routine health evaluations should proceed as directed by the health care professional performing the above routine screening.

I provide further detail on the above specialized testing. As set forth above, I am assuming that class members who meet the LCT are at an increased risk of developing cancers

detailed above. A disease appropriate for screening should occur with a high frequency in the population being screened and have a readily available treatment with potential for cure that increases with early detection. Cancer surveillance programs should employ tests capable of detecting disease in its pre-clinical state, be safe to administer, be reasonable in cost, lead to improved health outcomes and both test and treatment should be available. Surveillance guidelines specific to cancer type have been developed which fulfill these objectives in various high-risk subsets of the general population which balance the risks and benefits of testing. In the following discussion, I identify at risk groups within the general population with cancer risk as an analogous model for those with who meet the LCT.

Galleri® (Grail's Multi-Cancer Early Detection Blood Test) or similar Liquid Biopsy Testing
It is important to note that Galleri® has been shown to detect certain cancers, such as pancreatic and esophageal cancer which are among the cancers meriting monitoring here, which currently lack screening tests, and which account for a large number of US cancer deaths.

Colonoscopy and Fecal DNA testing
The risk for developing colon or rectal cancer rises quickly during the 5th and 6th decades of life. Thus, surveillance guidelines suggest colon cancer screening for average risk men and women 45 - 50 years of age and older. However, for higher risk groups, recommendations include initial testing earlier in life and more frequently thereafter. It is important to consider that colonoscopy is both a screening test and a therapeutic intervention. Precancerous polyp removal decreases colorectal cancer incidence.

The Multi-Society Task Force of Colorectal Cancer (MSTF), represents the American College of Gastroenterology, the American Gastroenterological Association, and The American Society for Gastrointestinal Endoscopy. For those at average risk, recommendations are colonoscopy every 10 years and annual fecal immunochemical test (FIT). For those unwilling or unable to undergo colonoscopy, guidelines suggest CT colonography every 5 years, the FIT-fecal DNA test every 3 years, and flexible sigmoidoscopy every 5 to 10 years. These later tests are appropriate screening tests, but each has disadvantages relative to the tier 1 tests. Because of limited evidence and current obstacles to use, capsule colonoscopy every 5 years is a least favored test. Screening should begin at age 50 years in average-risk persons, except in African Americans in whom limited evidence supports screening at 45 years. Persons with a family history of colorectal cancer (CRC) or a documented advanced adenoma in a first-degree relative age < 60 years, or two first degree relatives with these findings at any age, are recommended to undergo screening by colonoscopy every 5 years, beginning 10 years before the age at diagnosis of the youngest affected relative or age 40, whichever is earlier.

In my opinion, a class member who meets the meet the LCT should be screened for colorectal cancer similar to a person at increased risk due to colorectal cancer or advanced adenoma in a first degree relative. I make this recommendation based on comparison of relative risk of the two groups. A person with a first degree relative with colorectal cancer has an approximate relative risk of 1.8 – 2.67 (Cancer Causes Control (2013) 24:1207–1222, Journal of the National Cancer Institute, Vol. 86, No. 21, November 2, 1994) vs. a similar person without colorectal cancer in a first degree relative. Relative risk cancer after meeting the LCT for NDMA exposure vs. non-exposed is 0.99 – 2.12 (Madigan pg. 5). My opinion is that a person exposed

who meets the LCT should undergo colonoscopy at identification and every 5 years thereafter and Fecal DNA testing (such as Cologuard) yearly regardless of age. For a person who meets the 54-point threshold with other risk factors, either at the time of identification as new risks are identified, the schedule should be determined by screening standards for those risk factors, and subject to the judgment of the patient's physician.

Upper Endoscopy

At risk for esophageal cancer are those identified as having Barret's esophagus. Compared with the risk in the general population, the relative risk of adenocarcinoma among patients with Barrett's esophagus was 11.3. In patients with multiple risk factors associated with esophageal adenocarcinoma (age 50 years or older, male sex, white race, chronic GERD, hiatal hernia, elevated body mass index, and intra-abdominal distribution of body fat), guidelines suggest consideration of screening upper endoscopy, with risk and benefits individualized. (Volume 81, No. 6: 2015 GASTROINTESTINAL ENDOSCOPY 1305).

Plaintiffs' experts estimate RR 1.32-1.34 of gastric cancer and 1.27 for esophageal cancer in those class members who meet the LCT. This is within the range of risk for which endoscopic surveillance is considered. My recommendation in an asymptomatic patient is for an upper endoscopy every five years.

Low Dose CT Chest Scan

Plaintiff experts estimates RR 1.05 – 3.3 for lung cancer in those exposed to NDMA who meet the LCT. Given the risks associated with low dose CT scanning of the lungs, the lack of other viable screening modalities and the high risk for lung cancer that justifies the risks of screening in national guidelines, I recommend that screening for lung cancer should be conducted, via Low Dose CT Chest Scan, annually, which is the same frequency recommended by the USPSTF for long-time smokers.

6. Defense Expert Opinions

I understand that the manufacturers have retained expert witnesses who dispute that NDMA and NDEA at the levels confirmed, in the dosages confirmed, for the duration of use at issue, did or will increase the risk of cancer for people taking the contaminated pills. For example, I have reviewed the report of my esteemed colleague, Daniel Catenacci, M.D., including his opinions disputing the need for screening in this population. I have taken his analysis into account; however, I certify that the monitoring proposals detailed above have the potential to significantly improve the outcomes of patients that may be destined to develop malignancies due to their exposures and do not pose any significant risks or negative consequences as detailed in Dr. Catenacci's report. Furthermore, Dr. Catenacci does not address the Galleri test or similar liquid biopsy tests in his report.

7. Conclusion

It is my opinion to a reasonable degree of medical certainty that there exist diagnostic tests that can mitigate the risks of developing cancer faced by the class of people because of their exposure to contaminated valsartan (who meet the LCT), that this program is different than the one that would have been prescribed in the absence of that particular exposure and increased risk, and that it is reasonable and necessary. I understand that additional documents, statements,

depositions, or trial testimony on topics relevant to the opinions issued in this report may be forthcoming. As a result, I reserve the right to supplement this report or to address any such materials at trial or deposition.

Edward H. Kaplan, M.D.
Board Certified Medical Oncologist
Assistant Professor of Medicine, Rush University, Chicago, IL

November 10, 2021

Exhibit A

CURRICULUM VITAE

EDWARD H. KAPLAN, M.D.

OFFICE ADDRESS: Edward H. Kaplan, MD and Associates
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Skokie, IL 60076 (Start 7/1995)
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ACADEMIC APPOINTMENTS:

Assistant Professor of Medicine
1988-present
Rush Medical College

HOSPITAL AFFILIATIONS:

Rush-Presbyterian-St. Luke's Med. Ctr.
1988-present
Chicago, Illinois

North Shore University Health Care Systems (formerly, Rush North Shore Medical Center) 1988-present
Skokie, Illinois

Northwestern-Lake Forest Hospital
2007-present
Lake Forest, Illinois

Advocate Lutheran General Hospital
2012-present
Park Ridge, Illinois

EDUCATION:

B.Sc. in Biology 1978
University of Illinois
Urbana, Illinois

M.D.
1982

Loyola-Stritch School of Medicine
Maywood, Illinois

CURRICULUM VITAE
EDWARD H. KAPLAN, M.D.

CLINICAL TRAINING:

	Internship: Department of Internal Medicine
1982-83	
	Northwestern University Medical School Chicago, Illinois
	Residency: Department of Internal Medicine
1983-85	
	Northwestern University Medical School Chicago, Illinois
	Fellowship: Section of Hematology/Oncology
1985-88	
	Northwestern University Medical School Chicago, Illinois

MEDICAL LICENSURE:

	Illinois

CERTIFICATION:

	National Board of Medical Examiners
1983	
	American Board of Internal Medicine
1985	

American Board of Internal Medicine-
1987
Medical Oncology

MEMBERSHIPS:

American Society of Clinical Oncology
American College of Physicians
American Medical Association
Chicago Medical Society
Illinois State Medical Society

HONORS AND AWARDS:

Phi Eta Sigma
1974
University of Illinois

Galter Fellow
1986
Northwestern University Medical School
Chicago, Illinois

Bill Veek Fellow
1987
Northwestern University Medical School
Chicago, Illinois

Teaching and Service Award, finalist
1991
Rush-Presbyterian-St. Luke’s Med. Ctr.
Department of Internal Medicine

SERVICE AND ADMINISTRATIVE EXPERIENCE:

Chairman
1992-2010

Department of Hematology and Oncology
Rush North Shore Medical Center
Skokie, IL

Medical Director
1992 - 2011
Oncology Inpatient and Outpatient Unit
Rush North Shore Medical Center
Skokie, IL

Chairman 1992-1998
Investigational Review Board
Rush North Shore Medical Center
Skokie, IL

Director, Comprehensive Center
1990-1994
Gastrointestinal Malignancies
Rush Cancer Institute
Chicago, IL

Educational Coordinator
1988-1989
Section of Medical Oncology
Rush Medical College

Director
1988-1989
Inpatient Oncology Unit
Rush-Presbyterian-St. Luke’s Med. Ctr.
Chicago, Illinois

SERVICE AND ADMINISTRATIVE EXPERIENCE (CONTINUED):

Vice-President
1989-1993
American Cancer Society
Illinois Division (North Shore Branch)

Member, Illinois Cancer Council
1988-1992
(GI and Biologics Committees)

Member
1993-1994
Tumor Committee

	Rush University	
	Member, American Cancer Society	
1988-present	Illinois Division (North Shore Branch) Board of Directors	
	Member, Easter Cooperative Oncology	
1988-present	Group (GI Committee)	
	Reviewer	
1989-present	Journal of the National Cancer Institute	
	Reviewer, Cancer; A Journal	
1991-present	of the American Cancer Society	
	Member, Investigational Review Board	
1992-2009	Rush North Shore Medical Center	
	Member, Pharmaceutical and	
1999-2009	Therapeutic Committee Rush North Shore Medical Center	
	Member, Cancer Committee	
1997-2009	Rush North Shore Medical Center	
Member, Board of Health Village of Skokie		2004-2014

PATENTS:

1. Methods for Treatment of Neuro- and Nephro-Disorders and Therapeutic Toxicities using Aminothiol Compounds. Patent #: 5,994,409. Date: Nov. 30, 1999
Inventors: Martin Stogniew, David S. Alberts and Edward H. Kaplan.
Assignees: U.S. Bioscience, Inc. and The Arizona Board of Regents on behalf of the University of Arizona.

PATENTS (continued):

2. Methods for Treatment of Nephro-Disorders using Aminothiol Compounds.
Patent #: 6,586,476 B1. Date: July 1, 2003.
Inventors: Martin Stogniew, David S. Alberts, and Edward H. Kaplan.
Assignee: Medimmune Oncology, Inc.

3. Methods for Treatment of Neuro-Disorders using Aminothiol Compounds.
Patent #: 7,105,575 B2. Date: Sep. 12, 2006.
Inventors: Martin Stogniew, David S. Alberts, and Edward H. Kaplan.
Assignee: Medimmune Oncology, Inc.

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2. Citrin DL, Wallermark C, Nadler R, Geiger C, Tuttle K, Kaplan EH, Hauk W: Estramustine affects bone mineral metabolism in metastatic prostate cancer. Cancer 58:2208-2213, 1986.

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4. Zimmer AM, Rosen ST, Spies SM, Goldman-Leikin R, Kazikiewicz JM, Kaplan EH: Radioimmunotherapy retreatment of patients with cutaneous T-cell lymphoma using an 131I-labeled monoclonal antibody: Analysis of retreatment following plasmapheresis. Journal of Nuclear Medicine 29:174-180, 1988.

5. Kaplan EH, Goldman-Leikin RE, Radosevich JA, Rosen ST: Current status of monoclonal antibodies in cancer therapy. In: Cancer and Aging. Springer Publishing Co. 86-109, 1989.

6. Rosen ST, Kaplan EH, Zimmer AM: The therapeutic use of monoclonal antibodies in malignant lymphomas. Immunopathology and Immunotherapy Letter. 4:3-14, 1988.

7. Goldman-Leikin RE, Kaplan EH, Zimmer AM, Kazikiewicz J, Rosen ST: Long-term persistence of human anti-murine antibody responses following radioimmunotherapy of

cutaneous T-cell lymphoma patients using 131I-T101. Experimental Hematology 16:861-864, 1988.

CURRICULUM VITAE

EDWARD H. KAPLAN, M.D.

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PUBLICATIONS (CONTINUED):

8. Spies WG, Zimmer AM, Robinson PG, LoCicero J, Radosevich JA, Kaplan EH, Canade AB, Manzel L, Spies SM, Maguire RT, Rosen ST. Monoclonal antibody imaging using In-111labeled B72.3 in human non-small lung carcinoma. Radiology 169(p):74, 1988.

9. Zimmer AM, Kaplan EH, Kazikiewicz JM, Goldman-Leikin R, Gilyon KA, Dykewicz MS, Spies WG, Silverstein EA, Spies SM, Rosen ST: Pharmacokinetics of 131I-T101 monoclonal antibody in patients with chronic lymphocytic leukemia. Antibody Immunoconjugates and Radiopharmaceuticals 1:291-303, 1988.

10. Kaplan EH: The diagnostic and therapeutic use of monoclonal antibodies in colorectal cancer-current status. In: Hematology/Oncology Clinics of North America. Large Bowel Cancer. Vol. 3(1), eds: Harris SE and Levin B: 125-134, 1989.

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CURRICULUM VITAE
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CURRICULUM VITAE
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-9-

ABSTRACTS:

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infusion 5-flourouracil as third-line chemotherapy + radiotherapy for advanced breast cancer. 12th Annual San Antonio Breast Cancer Symposium. 1989 (Poster).

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ABSTRACTS (CONTINUED):

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Mitoxantrone-Based Regimen Followed by Involved Field Radiotherapy. Blood vol.
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INVITED LECTURES AND PRESENTATIONS:

1. Ovarian cancer. Grand Rounds; Rush Medical College. October, 1988.

2. Update on Monoclonal Antibodies in the Diagnosis and Treatment of Malignancies.
Medical Oncology Lecture Series, Rush-Presbyterian-St. Luke's Medical Center.
January, 1989.

3. DNR Status Relating to the Concerns of Nursing. Rush-Presbyterian-St. Luke's Medical Center. January, 1989.

4. Monoclonal Antibodies in Cancer. Grand Rounds; Rush Medical College. August, 1989.

5. Predictive Chemotherapy Sensitivity Testing. Holy Cross Hospital Tumor Board, Chicago, IL. September, 1989.

6. Recurrent Carcinoma of the Cervix. Clinical Tumor Conference, Rush North Shore Medical Center, Skokie, IL. September, 1989.

7. Chemosensitivity Assays. Northwest Community Hospital, Tumor Board, Arlington Heights, IL. October, 1989.

8. Monoclonal Antibodies in Diagnosis and Treatment of Cancer. MacNeal Hospital Grand Rounds, Berwyn, IL. October, 1989.

9. Predictive Chemotherapy Sensitivity Testing. Our Lady of the Resurrection Hospital
Tumor Board, Chicago, IL. November, 1989.

10. Monoclonal Antibodies and the Treatment of Lymphoreticular Tumors. Lymphoma Conference; Rush University. November, 1989.

11. Recurrent Embryonal Rhabdomyosarcoma. Clinical Tumor Conference, Rush North Shore Medical Center, Skokie, IL. December, 1989.

12. Gastrointestinal Lymphomas. Clinical Pathological Conference; Rush University. Chicago, IL. February, 1990.

INVITED LECTURES AND PRESENTATIONS (CONTINUED):

13. Predictive Chemotherapy Sensitivity Testing. Christ Hospital Tumor Board, Oak Lawn, IL. February, 1990.

14. Radioimmunodetection of Colon Cancer. Medical Oncology Lecture Series. Rush-Presbyterian-St. Luke's Medical Center. March, 1990.

15. Implications of Extreme Drug Resistance (EDR) in Cancer Chemotherapy. Silver Cross Hospital Tumor Board, Joliet, IL. April, 1990.

16. Implications of Extreme Drug Resistance in Cancer Chemotherapy. Rush North Shore Medical Center Tumor Board, Skokie, IL. April, 1990.

17. Diagnosis and Treatment of Colon Cancer. St. Joseph Medical Center Tumor Board, South Bend, IN. April, 1990.

18. Extreme Drug Resistance; The Rush Experience. Medical Oncology Lecture Series. Rush-Presbyterian-St. Luke's Medical Center. August, 1990.

19. Current Advances in Metastatic Colon Cancer. Grand Rounds; Rush Medical College. August, 1990.

20. Neoplastic Diseases and Antineoplastic Therapy. Sandoz Pharmaceuticals Oncology Training Seminar; Chicago, IL. October, 1990.

21. Management of Pain in the Cancer Patient. Hospital Grand Rounds; Grant Hospital Chicago, IL. February, 1991.

22. Chronic Pain Management for the Cancer Patient. Hospital Grand Rounds; West Suburban Hospital, Oak Park, IL. March, 1991.

23. Chemosensitivity and Chemoresistance Assays. Medical Oncology Conference-University of Miami School of Medicine; Miami, Fl. March, 1991.

24. Background on Common Malignancies. Concepts in Cancer and Cancer Therapy Seminar, (Nursing Program) Rush North Shore, Skokie, IL. April, 1991.

25. The Use of Monoclonal Antibodies in Cancer. Clinical Tumor Conference; Rush North Shore Medical Center, Skokie, IL. February, 1992.

26. The Management of Pain in the Cancer Patient. Medical Grand Rounds; Elmhurst

Memorial Hospital. Elmhurst, IL. May, 1992.

27. The Management of Pain in the Cancer Patient. Clinical Cancer Conference; Carle Clinic, Champaign, IL. June, 1992.

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INVITED LECTURES AND PRESENTATIONS (CONTINUED)

28. Position Emission Tomography (PET) Scanning in Clinical Oncology. Rush University, Oncology Lecture Series, Chicago, IL. February, 1993.

29. Radiolabeled Monoclonal Antibody Scanning in Colorectal Carcinoma. Rush University Oncology Lecture Series. Chicago, IL. May, 1993.

30. Use of Monoclonal Antibodies in the Clinical Practice of Oncology. Westlake Community Hospital Tumor Board. Melrose Park, IL. June, 1993.

31. OncoScint Cyt-103. A New Modality in Detection of Colorectal and Ovarian Cancer. Hinsdale Hospital Grand Rounds; Hinsdale, IL. July, 1993.

32. OncoScint CR/OV. A New Imaging Agent for Determining the Extent Location of Colorectal and Ovarian Adenocarcinomas. Outside Presentation, Chicago, IL. July, 1993.

33. Chemoresistance & Chemosensitivity Assays in the Treatment of Cancer. Oncology Conference (CME). St. Mary’s Hospital, Livonia, MI. September, 1993.

34. Radiolabeled Monoclonal Antibody Imaging in Colorectal and Ovarian Cancer. Oncology Conference, Mayo Clinic, Rochester, MN. October, 1993.

35. Clinical Application of Monoclonal Antibodies in the Detection of Colorectal and Recurrent Ovarian Carcinoma. Medical/Surgical Grand Rounds (CME). Swedish American Hospital, Rockford, IL. October, 1993.

36. The use of Immunoscintigraphy in the Diagnosis of Colorectal and Ovarian Cancer. Hematology and Oncology Grand Rounds (CME); Wayne State University, Detroit MI. November, 1993.

37. Colorectal Carcinoma; Early Detection and Adjuvant Therapy. Medical Grand Rounds (CME). St. Francis Hospital of Evanston, Evanston, IL. November, 1993.

39. Cancer in Women: Screening, detection and treatment. Hadassah Day at Rush North Shore Medical Center, Skokie, IL. November, 1993.

40. Colorectal Carcinoma-A Clinical Update. Rush University Oncology Lecture Series, Chicago, IL. November, 1993.

41. Treatment of Colon Cancer. Rush Cancer Institute Clinical Lecture Series. Chicago, IL. February, 1994.

42. Clinical Application of Monoclonal Antibodies in the Detection of Colorectal and Recurrent Ovarian Carcinoma. The Seventh Annual Oncology Nursing Conference. Rush Cancer Institute, Chicago, IL. March, 1994.

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INVITED LECTURES AND PRESENTATIONS (CONTINUED):

43. Monoclonal Antibody Nuclear Imaging of Colorectal and Ovarian Cancers. Copley-Mercy (CME) Consortium, Copley Memorial Hospital, Aurora, IL. March, 1994.

44. Radiolabeled Monoclonal Antibody Imaging for Colorectal and Ovarian Cancer (CME). St. Clair Hospital, Pittsburgh, PA. May, 1994.

45. Novel Treatment Strategies for Pancreatic Cancer. First RUSH Update on Gastrointestinal Cancers. RUSH University, Chicago, IL, September, 2005.

46. Identifying and Managing Hereditary Breast and Ovarian Cancer. CME Symposium; Sponsored by Myriad Labs: Vernon Hills, IL, February, 2008.

47. Hereditary Breast and Ovarian Cancer. Cancer Treatment Centers of America-Clinical Care Conference (CME), Zion, IL, December, 2008.

48. Hereditary Breast and Ovarian Cancer Sydrome- Integrating Genetic Testing into a Medical Oncology Practice. Sponsored by Myriad Labs: Joliet, IL, June, 2009.

49. Hereditary Breast and Ovarian Cancer. Medical Grand Rounds- Mt. Sinai Medical Center (CME): Chicago, IL, September, 2009.

50. Identifying and Managing Hereditary Breast and Ovarian Cancer. CME Symposium; Sponsored by Myriad Labs: Saginaw, MI, November, 2009.

51. Genetic Testing for Breast, Ovarian and Colorectal Cancer Prediction, Surveillance, and Disease Management. Physician Grand Rounds (CME- University of Illinois College of Medicine), Normal, IL, May, 2010.

52. An In Depth Look at Lung Cancer- Chemotherapy. Lake Forest Hospital Tumor Board, Lake Forest, IL, October, 2010.

53. Identifying and Managing Hereditary Cancer Syndromes. Local Oncology Group Symposium. Wichita, Kansas, October, 2010.

54. Genetic Testing for Hereditary Cancer and Personalized Medicine Prediction. Dinner Presentation. West Fargo, North Dakota, February, 2011.

55. Identifying and Managing Hereditary Cancer Syndromes. Medical Grand Rounds, Lake Region Healthcare, Fergus Falls, Minnesota, February, 2011.

56. Maximizing 5-FU Therapy for Colorectal Cancer Patients Using OnDose- Webinar; Sponsored by Myriad Labs: Broadcast September 8, 2011 and September 13, 2011.

57. Therapeutic Drug Monitoring for 5FU- a Rational Approach to Personalized Medicine.
OnDose Advisory Board Meeting. Chicago, May 31, 2012.

INVITED LECTURES AND PRESENTATIONS (CONTINUED):

58. Targeting A Personalized Patient Dose. Personalizing Medicine: 5FU Dosing in Colorectal Cancer. Featured speaker, with Ed Chu, MD, at independent CME Conference (Global Education Group) given during ASCO; Chicago, June 3, 2012.

Exhibit B

List Of Materials Considered

- 2021.07.06 Report of Dr. Mahyar Etminan
- 2021.07.06 Report of Dr. Stephen Hecht
- 2021.07.26 Report of Dr. Stephen Lagana
- 2021.07.07 Report of Dr. David Madigan
- 2021.07.06 Report of Dr. Dipak Panigrahy
- Medical Monitoring Third Amended Complaint
- 2021.08.27 Report of Dr. Daniel Catenacci
- Klein E, et al. Clinical validation of a targeted methylation-based multi-cancer early detection test. Oral presentation at: American Association for Cancer Research; April, 2021; LB013.
- E A Klein 1, D Richards 2, A Cohn, et al. Ann Oncol. 2021 Sep;32(9):1167-1177.doi: 10.1016/j.annonc.2021.05.806. Epub 2021 Jun 24.
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- Chen, X., et.al.: Prognostic Significance of Blood-Based Multi-cancer Detection in Plasma Cell-Free DNA. Clin Cancer Res. 2021 Aug 1;27(15):4221-4229. doi: 10.1158/1078-0432.CCR-21-0417. Epub 2021 Jun 4.
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- https://grail.com/press-releases/grail-announces-significant-progress-with-multi-cancer-early-detection-test-including-fda-breakthrough-device-designation/
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- https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening